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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,725	07/15/2003	Gregory M. Lanza	532512000401	1157

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,725

Applicant(s)

LANZA ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-79 and 82-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-79 and 82-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response dated 7-11-05 is acknowledged. In view of inadvertent omission of claims 87-93 the previous action is vacated. Claims included in the prosecution are 71-79 and 82-93.

Applicant is requested to include the continuation data on the first page of the specification.

Double Patenting

In view of the terminal disclaimer, the double patenting rejection is withdrawn.

Claim Rejections - 35 USC ' 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 71-79 and 82-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanza (5,690,907) or Lanza (5,780,010) or Lanza (5,958,371) of record.

Lanza in these patents discloses a method of delivery of an active agent to the target site using the same emulsions. The emulsions are oil-in-water emulsions

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containing a ligand (avidin, antibodies), an active agent, and perfluorooctylbromide.

The particles are coated with a lipid/surfactant. The lipids include phospholipids such as phosphatidylcholine, fatty acids (anionic) and stearylamine (cationic). It should be noted that applicant views phosphatidylcholine (1,2 diacyl-sn-glycerol-3-ethylphosphocholine) as a cationic lipid (see original canceled claim 15).

The particles are of instant sizes (note the abstract, col. 4, line 10 through col. 6, line 46. Col. 7, line 48 et seq., Examples and claims of 907; col. 4, line 25 through col. 8, line 9, Examples and claims of 010 and 371).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant amends the claims and argues that the only discussion of biologically active agents associated with the particles described in the cited art that applicants are able to find is in column 7 of the 907 patent, beginning at line 48, at column 7, beginning at line 60 in 010 and 371 patents. According to applicant this description says merely that biologically active agents (including drugs) are incorporated in the liquid encapsulated particles and become part of the conjugate bound to a specific biological surface for therapeutic action and there is no description which requires that the drug be present in the lipid surfactant layer. These arguments are not found to be persuasive since it is known in the art that the lipophilic agents get incorporated in the lipid bilayer of the liposomes and the hydrophilic agents in the interior. The examiner cites the references of in this context. The presence of active agent in the lipid layer in the references teachings thus, is implicit.

Applicant's arguments have been fully considered, but are not found to be persuasive. In response to the examiner's previous position, applicant argues that the present compositions are not liposomes and there is no aqueous interior or bilayer and that both the interior of the particles and the lipid/surfactant outer layer are both hydrophobic. These arguments are not found to be persuasive since whether the lipid layer is a bilayer or single layer, the property of the lipophilic compounds is to sequester into the lipid. Instant claims do not recite the nature of the active agents. Therefore, the presence of a lipophilic agent in both the hydrophobic interior and the lipid layer is implicit in the references of Lanza. Instant claims do not exclude the presence of the active agent in the interior.

Claim Rejections - 35 USC ' 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 71-79 and 82-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanza (5,690,907) or Lanza (5,780,010) or Lanza (5,958,371) by themselves or in combination with either Adler Moore (5,656,287).

The teachings of Lanza 907, 010 and 371 have been discussed above. What is lacking in Lanza is the explicit teaching that the active agents are incorporated in the lipid layer and the claimed active agents in claims 87-93. However, since a lipophilic active agents such as taxanes and doxorubicin have a tendency to dissolve in lipid material and not in an aqueous medium, it would have been obvious to one of ordinary skill in the art that the active agents taught by Lanza would be in the lipid layer.

Adler Moore while disclosing the liposomal preparation of cyclosporin teaches that water-soluble molecules get incorporated into the aqueous interior and the lipophilic molecules will tend to be incorporated into the lipid layer. The process of preparation is similar to instant process (see instant example 1), that is, dissolving the phospholipid and the lipophilic active agent in chloroform, drying the lipid mixture and the addition of the aqueous layer (col. 2, lines 31-54).

It would have been obvious to one of ordinary skill in the art that the lipophilic active agents in Lanza are trapped in the lipid layer since similar method involving organic solvent and the addition of an aqueous medium to the lipid mixture containing the lipophilic active agent results in the incorporation of the agent in the lipid layer as evident from Adler Moore.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant pointing to Example 1 in the specification, once again argues that instant preparations are not liposomes. These arguments have been addressed above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

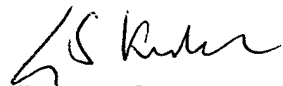
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK